

Docket No.: **515-4218**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT OPERATIONS

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In re Application of:

**Achile Arini, et al.**

Serial No.: 09/815,533

Filed: March 16, 2001

)  
)  
) Group Art Unit: 1652  
)  
) Examiner: Steadman, David J.  
)

**For: A METHOD FOR THE PRODUCTION OF PHARMACEUTICALLY ACTIVE RECOMBINANT PROTEINS**

New York, NY 10036  
December 4, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is being filed under the provisions of 37 CFR§1.97.

|  |   |
|--|---|
| EPO Search Report  | Lists references cited by the Examiner.   |
| Cell Structure and Function vol. 14 no. 5, Pgs 579-586 (1989)                      | Disclose effect of butyrate on expression of human preproinsulin.                               |
| Biotechnology and Bioengineering Vol. 55 No.2 (1997)                               | Discloses use of fermentor temperature for control of high-density cultures of mammalian cells. |
| Journal of Biological Chemistry vol.263, no. 7 Pgs 3063-3066(1988)                 | Discloses secretion of soluble functional insulin receptors of NIH3T3 cells.                    |
| Proceeding of the National Academy of Sciences USA Vol.85 No. 1 Pgs 126-130 (1988) | Discloses expression of human epidermal growth factors precursor.                               |

Proceeding of the  
National Academy of  
Sciences USA Vol.93 No. 1  
Pgs 65-70 (1996)

Discloses method of producing human lysosomal  
acid  $\alpha$ -glucosidase.

EP 0 180 859 A2

Cited by the Examiner.

DE 28 15 853 A1

Cited by the Examiner.

WO 00/65070

Discloses cell culture process.

WO 00/00624

Discloses production of urokinase.

Australian Official Action

Lists references cited by Australian Examiner.

FR 900.826

Discloses use of E. coli clone in the production of  
preprourokinase.

WO 90/04023

Discloses production of human preprourokinase.

The Journal of Biological  
Vol. 266, No.8 Pgs 5147-  
5152 (1991)

Discloses activation of prpenzyme urokinase-type  
plasminogen activator.

The Journal of Biological  
Vol. 267, No.6 Pgs 3878-  
3885 (1992)

Discloses domain structure and interactions of  
recombinant Urokinase-type plasminogen activator.

The Journal of Biological  
No.8 Pgs 17120-  
17126 (1986)

Discloses purification of a novel low molecular  
weight urokinase plasminogen activator.

Applicant petitions for consideration the attached prior art under 37  
CFR 1.97. Authorization is given to charge Deposit Account No. 08-1540 for the  
acquired fee.

Respectfully submitted,



James V. Costigan

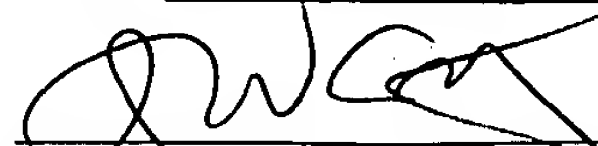
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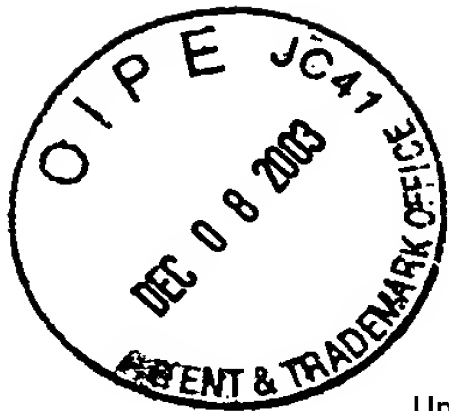
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James V. Costigan, Registration No. 25,669



PTO/SB/08A (10-01)  
Approved for use through 10/31/2002. OMB 0651-0031  
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |      | Application Number       | 09/815,533          |
|   |      | Filing Date              | March 16, 2001      |
|   |      | First Named Inventor     | Achile Arini, et al |
|   |      | Art Unit                 | 1652                |
|   |      | Examiner Name            | Steadman, David J.  |
| Sheet 1   | of 1 | Attorney Docket Number   | 515-4218            |

| U.S. PATENT DOCUMENTS |            |  |                                |  |   |
|-----------------------|------------|--|--------------------------------|--|---|
| Examiner Initials*    | Cite No. 1 | Document Number                            | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                       |            | Number - Kind Code <sup>2</sup> (if known) |                                |  |   |
|                       | AA         | US-  |                                |  |   |
|                       | AB         | US-  |                                |  |   |
|                       | AC         | US-  |                                |  |   |
|                       | AD         | US-  |                                |  |   |
|                       | AE         | US-  |                                |  |   |
|                       | AF         | US-  |                                |  |   |
|                       | AG         | US-  |                                |  |   |
|                       | AH         | US-  |                                |  |   |
|                       | AI         | US-  |                                |  |   |
|                       | AJ         | US-  |                                |  |   |
|                       | AK         | US-  |                                |  |   |
|                       | AL         | US-  |                                |  |   |
|                       | AM         | US-  |                                |  |   |
|                       | AN         | US-  |                                |  |   |
|                       | AO         | US-  |                                |  |   |
|                       | AP         | US-  |                                |  |   |
|                       | AQ         | US-  |                                |  |   |
|                       | AR         | US-  |                                |  |   |
|                       | AS         | US-  |                                |  |   |
|                       | AT         | US-  |                                |  |   |

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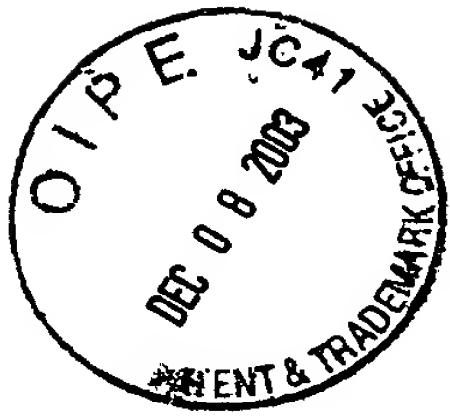
| FOREIGN PATENT DOCUMENTS |            |   |                                |  |   |                |
|--------------------------|------------|---|--------------------------------|--|---|----------------|
| Examiner Initials*       | Cite No. 1 | Foreign Patent Document   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup> |
|                          |            | Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known) |                                |  |   |                |
|                          | AU         | EP 0 180 859  | 5/14/1996                      | Behringwerke AG                                    |   |                |
|                          | AV         | DE 28 15 853  | 10/19/1978                     | Choay SA   |   |                |
|                          | AW         | WO 00/65070   | 11/2/2000                      | Genentech Inc.                                     |   |                |
|                          | AX         | WO 00/00624   | 1/6/2000                       | Cropotech Devl. Corp.                              |   |                |
|                          | AY         | FR 900.826  | 10/16/1934                     |  |   |                |
|                          | AZ         | WO 90/04023   | 4/19/1990                      | Farmitalia Carlo                                   |   |                |
|                          | BA         |   |                                |  |   |                |
|                          | BB         |   |                                |  |   |                |
|                          | BC         |   |                                |  |   |                |
|                          | BD         |   |                                |  |   |                |

|                    |  |                 |  |
|--------------------|--|-----------------|--|
| Examiner Signature |  | Date Considered |  |
|--------------------|--|-----------------|--|

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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|   |   | Filing Date              | March 16, 2001      |
|   |   | First Named Inventor     | Achile Arini, et al |
|   |   | Group Art Unit           | 1652                |
|   |   | Examiner Name            | Steadman, David J.  |
|   |   | Attorney Docket Number   | 515-4218            |
| Sheet   | 2 | of                       | 2                   |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS |                          |   |                |
|--|--------------------------|---|----------------|
| Examiner<br>Initials                               | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup> |
|  | BE                       | EPO Search Report   |                |
|  | BF                       | Cell Structure and Function vol. 14 no. 5, Pgs 579-586 (1989)   |                |
|  | BG                       | Biotechnology and Bioengineering Vol. 55 No.2 Pgs 328-338 (1997)  |                |
|  | BH                       | Journal of Biological Chemistry vol.263, no. 7 Pgs 3063-3066 (1988)   |                |
|  | BI                       | Proceeding of the National Academy of Sciences USA Vol.85 No. 1 Pgs 126-130 (1988)  |                |
|  | BJ                       | Proceeding of the National Academy of Sciences USA Vol. 93 No. 1 Pgs 65-70 (1996)   |                |
|  | BK                       | Australian Official Action  |                |
|  | BL                       | The Journal of Biological Vol. 266, No.8 Pgs 5147- 5152 (1991)  |                |
|  | BM                       | The Journal of Biological Vol. 267, No.6 Pgs 3878- 3885 (1992)  |                |
|  | BN                       | The Journal of Biological No.8 Pgs 17120- 17126 (1986)  |                |
|  | BO                       |   |                |

|                       |  |                    |  |
|-----------------------|--|--------------------|--|
| Examiner<br>Signature |  | Date<br>Considered |  |
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